The Pursuit of Better Medicines through Genetic Research

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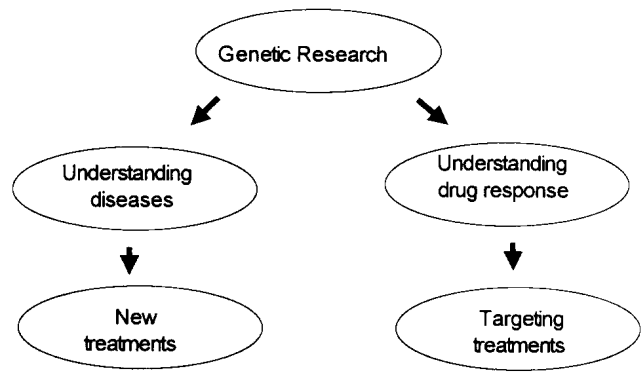
- Genetic research goals and initiatives at GSK
- Industry group addressing ethical, legal and regulatory issues with genetic research into drug response (pharmacogenetics)
- Research sponsor÷s perspectives on family consent and suggested points to be considered

Genetic Research Goals at GSK

- Use results of genetic research to discover new medicines acting on new targets (e.g., new genes associated with human disease pathway)
- Improve safety and efficacy of medicines by understanding the genetic basis for +/- drug response in individuals
- Promote education and informed discussion about genetic research
- Identify susceptibility genes for common diseases

Primary Genetic Research Initiatives



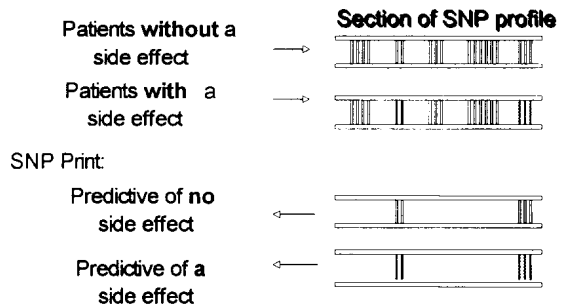
Identification of Disease Susceptibility Genes

- Susceptibility genes confer a risk of - but do not cause - disease
- GSK Clinical Genetics Networks
  - Large, international studies among academic institutions, genome screening centers and genetic epidemiology centers
  - Protocols with well-characterized, standardized patient assessment criteria
  - Detailed family history, clinical information and DNA from affected and unaffected siblings and parents
  - Informed consent and information coding
  - Identify gene loci responsible for disease susceptibility
  - Examples -- Asthma, Depression, COPD, Early Onset Heart Disease, Osteoarthritis

Pharmacogenetic Research

- Pharmacogenetics: How genetic differences among patients influence their responses to medicines
- GSK÷s Pharmacogenetic research in drug development trials
  - Participation is voluntary - separate consent for genetic research
  - Blood sample for DNA analysis and information coding
  - Correlate drug response with genotype information using pooled data

Pharmacogenetic research:



Pharmacogenetics Working Group

Mission: To advance the understanding and development of pharmacogenetics by openly addressing and disseminating information on non-competitive topics such as ethical, legal and regulatory issues.

Proposed Activities: Sponsor symposia, prepare publications, interface with US and European regulators and address elements of pharmacogenetic research protocols and consents

A Sponsor÷s Perspectives on Family Consent

- Distinction among types of research
- Implications for Study Participants
- Implications for the Feasibility of Research

Points to Consider regarding Family Consent

- Scientific rationale for collecting family history data
- Justification for the degree of detail
- Degree of confidence that subject is a credible source of family history
- Implementation of safeguards (data collection environment, access and release of data)

Recommendations regarding Family Consent

- Responsibility for assessing family consent issues should remain with local investigators, ethics committees and research sponsors
- Education and guidance materials - not prescriptive, sweeping measures - should be developed for use by researchers, ethics committees and sponsors